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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

MEHTA, ASHWIN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1638 | |

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/490,312 | WEBER, GERHARD P. |
| | Examiner | Art Unit |
| | Ashwin Mehta | 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8,20,33 and 41-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-7,33,51 and 52 is/are allowed.

6) Claim(s) 8,41-49 and 53-61 is/are rejected.

7) Claim(s) 20 and 50 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejections of claims 6, 11, 15, 19, 21, 28, 32-34, and 38-40 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim amendments or cancellations.
3. The rejection of claim 33 under 35 U.S.C. 112, 1st paragraph, is withdrawn in light of the deposit of inbred maize plants GE516214 and GE533139 with the ATCC, and the written assurance, in the paper submitted 14 April 2003 on page 12, that the remainder of the requirements of 37 CFR 1.821-1.825 at the time of allowance.

Claim Objections

4. Claims 20 and 50 are objected to for the following reasons:

Claims 20 and 50 are objected to under 37 CFR 1.75 (b) as being duplicate claims. Both claims are drawn to a maize plant, or its parts, having all the morphological and physiological characteristics of hybrid maize plant 39M27. Both claims have the same scope. Applicant is required to cancel one of the claims, or amend the claim(s).

Claim Rejections - 35 USC § 112

5. Claim 8 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 13 January 2003 under item 6. Applicant traverses the rejection in the paper filed 14 April 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that support can be found on pages 2 and 12, that there are several modes of conferring male sterility, and that one skilled in the art would not find the terminology indefinite (response, page 9, 5th full paragraph). However, the recitation "or other factors" in the passage on page 12 pointed out by Applicant, does not clearly define what the other factors are. Further, in the absence of a recitation indicating how the plant obtained the genetic factor, the claim broadens the scope of parent claim 2, which does not encompass a plant that is male sterile.

6. Claims 42-49, 53, 55, 59, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 42 and 47: the recitation "value added trait gene" in line 3 of the claims renders them indefinite. The specification does not clearly define the recitation. Page 33 provides examples of value added trait genes. However, the recitation "such as" in line 18 of page 33 does not provide a clear indication of what other genes are value added trait genes.

Further in claims 42 and 47: the claims are indefinite because there is improper antecedent basis for “The maize plant of claim 41 (or 45)” in line 1. Claims 41 and 45 are directed to methods, not maize plants.

In claims 43 and 48: the recitation “derivative thereof or a synthetic polypeptide modeled thereto” renders the claims indefinite. It is not clear what is considered to be a “derivative”, or what is encompassed by a polypeptide that is “modeled”. The metes and bounds of the claims are unclear.

In claim 45: the claim is indefinite because the last line of the claim is not consistent with the preamble. The first line of the claim indicates that the claim is directed to a method of developing a backcross conversion 39M27 hybrid maize plant. However, the last line indicates that a transgenic 39M27 hybrid maize plant is produced.

In claim 46: the recitation “said plant having received all of its alleles from maize hybrid plant 39M27” renders the claim indefinite. Line 2 of the claim indicates that the starting material is the plant produced from the method of claim 45, which does not produce hybrid plant 39M27.

In claim 53: the recitation “an inbred parent plant” in line 7 renders the claim indefinite. It is not clear if the inbred plant in the recitation is the same as the inbred plant in the recitation “said inbred parent” in line 5. The recitation “said inbred parent” in line 5 indicates that the collection of seed comprises seed of one, not both, of the inbred parents of hybrid 39M27.

In claim 55: the recitation “genetic identity” in line 2 renders the claim indefinite. It is not clear what is meant by this recitation: phenotypic traits, alleles, nucleotide sequences, etc. It is also not clear what is encompassed by “at least about”.

In claim 59: the claim is indefinite because it is dependent on itself.

In claim 60: the claim is indefinite because it does not recite any positive method steps. The preamble indicates that the claim is directed to a method for developing a maize plant in a maize plant breeding program. However, the remainder of the claim only indicates that the plant of claim 2 is to be used as starting material. There are no steps reciting how a maize plant is developed from any breeding program.

7. Claims 41-43, 45-49, 54-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 January 2003 under item 7 for claims 9-19, 22-32, and 34-40. Applicant traverses the rejection in the paper received 14 April 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that the new claims come within the purview of the written description requirement (response, page 11, 1st full paragraph). The new claims do not overcome the rejection because they retain the written description issues discussed for the claims previously rejected for lack of written description in the previous Office actions. Applicants also assert new claims 41-61 were placed in the format suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson and Examiner David Fox (page 9, 1st full paragraph). However, all of the newly submitted claims were not faxed to Applicant or suggested by SPE Nelson and Examiner Fox. Further, the specification also does not describe all types of genes that are considered to be

“value-added trait” genes. The specification mentions expressing the stearoyl-ACP desaturase gene in antisense orientation, to increase stearic acid content; introducing a gene encoding phytase to enhance phytate breakdown; and modifying carbohydrate content by transforming plants with a gene coding for an enzyme involved in starch branching pattern (page 33, line 18 to page 34, line 3). However, the specification does not describe what other genes are considered as “value-added trait” genes, nor is there any indication that other such genes have been isolated in the prior art. Page 33 of the specification also indicates that a gene responsible for lowering phytic acid content in maize can be cloned (page 33, lines 27-30). However, a method of isolation does not describe the gene itself. See Fiers 25 USPQ 2d (CAFC 1993) at 1606, which states that “[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”. Further, the only *Bacillus thuringiensis* gene encoding a polypeptide that can confer insect resistance described in the specification is the Bt δ -endotoxin gene. The specification does not describe any other *B. thuringiensis* polypeptides encoding insect resistance genes, or derivatives and synthetic polypeptides modeled after any *B. thuringiensis* polypeptide.

8. Claims 46, 54, and 55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 January 2003

under item 7 for claims 9-19, 22-32, and 34-40. Applicant traverses the rejection in the paper received 14 April 2003. Applicant's arguments have been fully considered but were not found persuasive.

In response to claims reciting double haploid methods, which was rejected as new matter in the last Office action, Applicant argues that the specification recites “[p]lant breeding techniques known in the art and used in a maize plant breeding program include, but are not limited to,...”, and that double haploid breeding is a technique long known and used in the art of plant breeding. Applicants argue that a specification need not include, and preferably omits, what is well known in the art, and cite *In re Myers* for support (response, page 11, 2nd full paragraph). However, the court in *In re Myers* affirmed the rejection of a non-original claim for reciting new matter, stating, “appellant may not specifically claim those two binders after his filing date for want of a specific disclosure even though they may be the most prevalently used” (page 674). Instant claims 46, 54, and 55 are rejected for reciting **NEW MATTER**. Further, the recitation “said inbred line comprises at least about 75% genetic identity to a line selected from the group consisting of GE516214 and GE533139” in claim 55 also is **NEW MATTER**, as the specification does not mention a method for producing any such inbreds having the stated at least about 75% genetic identity. Applicants should point to support for the phrases in the specification as filed, or delete the phrases from the claims. The specification does not even provide any description at all concerning the genotype or phenotype of GE516214 or GE533139.

9. Claims 45-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of developing a backcross conversion 39M27 hybrid maize plant, comprising backcrossing a gene into at least one of the inbred parents of 39M27, and crossing said inbred parents to produce a transgenic 39M27 hybrid maize plant.

The specification indicates that backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. Progeny would be homozygous for loci controlling the transferred characteristic, but will be like the superior parent for essentially all other genes (paragraph bridging pages 3-4).

However, the specification does not teach either inbred parent plant comprising only a single gene that has been introduced by backcrosses and retaining all of its genes and traits. It is not clear that single genes or single traits may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in

nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Further regarding claims 47 and 48: the specification does not teach what all gene types are that are considered to be "value added trait genes," and the term also encompasses genes that have not been isolated at the time the application was filed. The specification also does not teach derivatives or synthetic polypeptides modeled on any *Bacillus thuringiensis* polypeptide that confers insect resistance. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of transferring single genes by backcross breeding taught in the prior art.

10. Claims 41-43 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of transforming 39M27 when the transgene is known in the art and whose effect when expressed in transformed plants is known, does not reasonably provide enablement for the claimed method with all transgenes. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claim is broadly drawn towards a method of developing a transgenic 39M27 maize plant wherein inbred maize plant 39M27 is transformed with any transgene.

The specification teaches that inbred maize plants GE516214 and GE533139 are Pioneer Hi-Bred International, Inc. proprietary lines that were crossed to produce hybrid 39M27. Seeds of the inbred plants have been deposited with the ATCC (page 7, last paragraph; page 37). The specification discusses transformation of maize plants (paragraph bridging pages 24-25 to page 35, 3rd full paragraph).

However, the specification does not enable transforming maize plant the inbred parents of 39M27 with all transgenes. As broadly interpreted, the method encompasses introducing any type of transgene into plants, and, by crossing, into 39M27, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., *supra*. Further, if the effect of transgene expression in the inbred parents and 39M27 were unknown, one skilled in the art would not know how to use the plant produced by the claimed method. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed 39M27 are unknown. The specification does not teach one how to use a transformed 39M27 plant if all of the morphological and physiological traits of 39M27 are not expressed. Further regarding claims 42 and 43: these claims are included in the rejection as the specification does not teach what all gene types are that are considered to be

“value added trait genes,” and the term also encompasses genes that have not been isolated at the time the application was filed. Applicant does not provide guidance for any and all genes that confer traits on plants that add value to the plants. The specification also does not teach derivatives or synthetic polypeptides modeled on any *Bacillus thuringiensis* polypeptide that confers insect resistance. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., *supra*.

Regarding claim 53: the specification does not teach how to distinguish the inbred parent corn plants from hybrid 39M27 plants. The specification does not mention anything about the traits or other distinguishing characteristics of the inbred parent plants of 39M27. It is unclear how one skilled in the art can identify the inbred parent plants of 39M27 from other maize plants. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. Claims 1-7, 33, 51, and 52 are allowed. Claims 8, 41-49, and 53-61 are rejected. Claims 20 and 50 are objected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this

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application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



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June 26, 2003